

CLAIMS

That which is claimed is:

1. A control composition for a coagulation test, comprising:
 - (a) particles capable of aggregating in plasma; and
 - (b) calcium ions.
2. The control composition of claim 1, further comprising at least one optical contrast enhancer.
3. The control composition of claim 1, further comprising at least one aggregation enhancer.
4. The control composition of claim 1, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.
5. The control composition of claim 1, wherein said calcium ion source comprises a calcium halide.
6. The control composition of claim 1, further comprising plasma.
7. A control composition for a coagulation test, comprising:
 - (a) particles capable of aggregation in plasma;
 - (b) a solution of calcium ions; and
 - (c) plasma.
8. The control composition of claim 7, wherein said solution of calcium ions further comprises an optical contrast enhancer.
9. The control composition of claim 7, wherein said solution of calcium ions further comprises a dissolved dye.

10. The control composition of claim 7, wherein said solution of calcium ions further comprises hemoglobin.

11. The control composition of claim 7, wherein said particles are suspended in a solution comprising an antifreeze.

12. The control composition of claim 7, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

13. The control composition of claim 12, wherein said polymeric beads comprise polystyrene, and said charged functional groups comprise carboxylate groups.

14. The control composition of claim 12, wherein said polymeric beads contain a dye.

15. The control composition of claim 7, wherein said aggregation enhancer comprises hemoglobin.

16. A control composition for a coagulation test, comprising:

- (a) polymeric beads having charged functional groups on surfaces of said beads;
- (b) a solution of calcium ions; and
- (c) citrated plasma.

17. The control composition of claim 16, wherein said solution of calcium ions includes an optical contrast enhancer.

18. The control composition of claim 16, wherein said solution of calcium ions comprises a calcium halide solution.

19. The control composition of claim 16, wherein said aggregation enhancer comprises hemoglobin.

20. The control composition of claim 16, wherein said polymeric beads comprise polystyrene.

21. The control composition of claim 16, wherein said charged functional groups comprise carboxylate groups.

22. The control composition of claim 16, wherein said polymeric beads contain a dye.

23. The control composition of claim 16, wherein said suspension of polymeric beads further comprises an antifreeze.

24. The control composition of claim 16, wherein said solution of calcium ion further comprises a dissolved dye.

25. A method for evaluating a coagulation test, comprising:

- (a) providing a composition including calcium ions and particles capable of aggregating in plasma;
- (b) combining said calcium ions and said particles with plasma to form a control composition; and
- (c) introducing said control composition and said plasma to said coagulation test.

26. The method of claim 25, further comprising monitoring coagulation of said control composition.

27. The method of claim 26, further comprising determining a coagulation time for said control composition.

28. The method of claim 27, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

29. The method of claim 28, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

30. The method of claim 29, further comprising determining a calibration curve for said coagulation test.

31. The method of claim 25, wherein said coagulation test comprises a prothrombin time test.

32. The method of claim 25, wherein said providing said composition comprises:

- (a) providing a suspension of said particles;
- (b) providing a solution of said calcium ions; and
- (c) combining said suspension of said particles and said solution of said calcium ions.

33. The method of claim 32, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

34. The method of claim 25, wherein providing said composition comprises including at least one optical contrast enhancer in said composition.

35. A method for evaluating a coagulation test, comprising:

- (a) providing particles capable of aggregating in plasma;
- (b) providing a solution of calcium ions;
- (c) combining said particles and said solution of said calcium ions;
- (d) adding citrated plasma to said combined said particles and said solution of said calcium ions; and

- (e) introducing said combined citrated plasma, said particles, and said solution of said calcium ions to a coagulation test.

36. The method of claim 35, further comprising monitoring coagulation of said combined citrated plasma, said particles, and said solution of said calcium ions.

37. The method of claim 36, further comprising determining a coagulation time for said combined citrated plasma, said particles, and said solution of said calcium ions.

38. The method of claim 37, further comprising determining a relationship between said coagulation time of said combined citrated plasma, said particles, and said solution of said calcium ions, and a coagulation time of whole blood associated with said plasma in said control composition.

39. The method of claim 38, further comprising determining a relationship between said coagulation time for said combined citrated plasma, said particles, and said solution of said calcium ions, and a coagulation time using a reference test.

40. The method of claim 39, further comprising determining a calibration curve for said coagulation test.

41. The method of claim 35, wherein said solution of said calcium ions comprises an aggregation enhancer.

42. The method of claim 41, wherein said aggregation enhancer comprises hemoglobin.

43. The method of claim 35, wherein said particles comprise polymeric beads with charged functional groups on surfaces thereof.

44. The method of claim 35, wherein said solution of said calcium ions comprises a calcium halide solution.

45. The method of claim 35, wherein said providing said particles comprises suspending said particles in an antifreeze.

46. The method of claim 35, wherein said coagulation test comprises a prothrombin time test.

47. A coagulation test evaluation device comprising:

- (a) a container with first and second compartments;
- (b) particles capable of aggregating in plasma located within said first compartment; and
- (c) a solution of calcium ions located within said second compartment;
- (d) said container configured to allow said particles and said solution of said calcium ions to be combined together in said container.

48. The coagulation test evaluation device of claim 47, wherein said container is configured to allow a citrated plasma sample to be transferred into said container and added to said combined said suspension of said particles and said solution of said calcium ions.

49. The coagulation test evaluation device of claim 47, wherein said container further comprises a third compartment and a sample of citrated blood plasma located in said third compartment, said container being configured to allow said suspension of said particles, said solution of said calcium ions, and said sample of citrated blood plasma to be combined together in said container.

50. The coagulation test evaluation device of claim 47, wherein said first and second compartments comprise frangible hollow beads.

51. A kit for calibration of a coagulation test, comprising:

- (a) particles capable of aggregating in plasma;
- (b) a solution of calcium ions; and
- (c) a sample of citrated plasma.

52. The kit of claim 51, further comprising printed instructions for combining said suspension of said particles, said solution of said calcium ions, and said sample of said citrated blood plasma, introducing said combined said suspension of said particles, said solution of said calcium ions, and said citrated blood sample, to said coagulation test, determining a calibration curve for said coagulation test, and calibrating said coagulation test.

53. The kit of claim 51, further comprising a container with first and second compartments, said suspension of said particles located in said first compartment, and said solution of said calcium ions located in said second compartment, said container configured to allow said suspension of said particles and said solution of said calcium ions to be combined in said container.

54. The kit of claim 51, further comprising at least one coagulation test strip.

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